24. (three times amended) A method for making a composition for treating a patient to prevent or treat mucositis comprising

formulating an effective amount to prevent or treat mucositis of a [tetracyline] tetracycline in the form of a polyvalent metal ion complex which has less than 10% bioavailability when orally [adminstered] administered in a carrier for topical administration to the mucosa.

Remarks

Amendment to the claims

Claims 21 and 24 have been amended to correct typos contained therein.

Restriction requirement

Claims 1-11 and 13-24 were restricted into three groups of claims. Group I claims include claims 1-11, 13 and 14, drawn to a composition. Group II claims include claims 15-23, drawn to a method of treating. Group III includes a single claim, claim 24, drawn to a method of making. The applicants elect Group I claims, but respectfully traverse the restriction requirement.

The Group I claims define a composition that contains an effective amount of a poorly absorbed tetracycline in the form of a polyvalent metal ion complex in a carrier for topical administration wherein less than 10% of the tetracycline is absorbed into the systemic circulation when topically administered. The Group II claims define a method for treating a patient by administering to the patient a composition that contains an effective amount of a poorly absorbed tetracycline in the form of a polyvalent metal ion complex in a carrier for topical administration

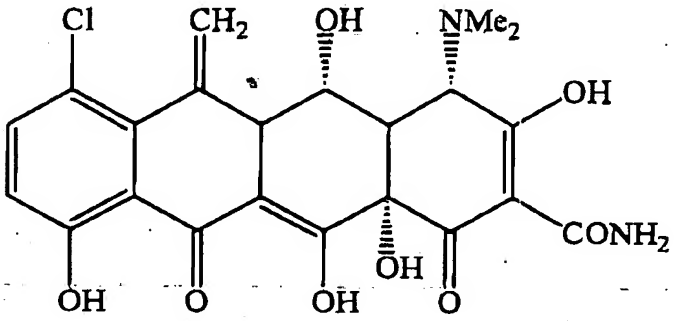
wherein less than 10% of the tetracycline is absorbed into the systemic circulation when topically administered. Both of the Group I claims and Group II claims include the following essential element: an effective amount of a poorly absorbed tetracycline in the form of a polyvalent metal ion complex in a carrier for topical administration wherein less than 10% of the tetracycline is absorbed into the systemic circulation when topically administered. Therefore, the method defined in any of the Group II claims cannot be practiced with another materially different composition. Conversely, the composition defined in any of the Group I claims cannot be used in a materially different method.

The Examiner asserted that the composition as claimed can be used in a materially different process such as treating acne. This assertion misreads the claims in the two groups of claims. None of the two groups of claims require the composition or the method defined therein to be limited to a specific disease. Therefore, whether the composition can be used in treating acne is not an issue, and the restriction of the Group I and Group II claims is unfounded.

The sole claim in Group III defines a method of making a composition. The method requires formulating an effective amount to prevent or treat mucositis of a tetracycline in the form of a polyvalent metal ion complex which has less than 10% bioavailability when orally administered in a carrier for topical administration to the mucosa. The Examiner asserted that the composition defined in any of the Group I claims can be prepared in the form of a complex of the tetracycline with an interferon, which is materially different from the method defined in claim 24. The applicants respectfully disagree.

As described at p. 8, lines 12-15, a polyvalent metal ion complex of a tetracycline provides a stable form of the tetracycline which is stable in contact of water at room temperature for a long period, e.g., two years or more. While tetracycline may form a complex with interferon, the interaction between the interferon and tetracycline molecules is certainly not in the form a coordinative binding as is in the polyvalent metal ion complex of the tetracycline. As such, a tetracycline/interferon complex would not be as stable as the polyvalent metal ion complex of the tetracycline. Therefore, the composition containing a tetracycline/interferon complex would be materially different from the composition containing a polyvalent metal ion complex of the tetracycline. As such, the restriction of the Group I and Group III claim is improper.

The applicants elect the species defined in claim 7 for prosecution. Claim 7 defines a single species having the following structure:



Withdrawal of the restrictions of the claims into the Group I, II, and III claims and allowance of all claims 1-11 and 13-24 are respectfully solicited.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the enclosed Amendment and all documents shown as being attached are being facsimile transmitted to the U. S. Patent and Trademark Office on the date shown below.

Date: December 23, 2002

Peggy Bailey